

PSJ3  
Exhibit 57F



## CONSULTING AGREEMENT

This CONSULTING AGREEMENT (the "Agreement") is made as of February 5, 2010 ("Effective Date") by and between Dr. Russell Portenoy, MD with an address at First Ave. at 16<sup>th</sup> Street, New York, NY 10003 ("Consultant") and Mallinckrodt Inc., a Delaware corporation and a Covidien company with offices located at 675 McDonnell Boulevard, Hazelwood, MO 63042 ("Mallinckrodt").

WHEREAS, Consultant possesses expertise in the areas of Pain and Addiction Medicine ("Consulting Field"), and wishes to make his/her expertise and efforts in the Consulting Field available to Mallinckrodt, and

WHEREAS, Mallinckrodt desires to engage the services of Consultant for the performance of certain specific tasks or projects to be specified by Mallinckrodt that are related to the Consulting Field on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of these premises and the promises set forth herein, Mallinckrodt and Consultant hereby agree as follows:

### 1. Engagement of Consultant.

- 1.1. Mallinckrodt hereby engages Consultant, and Consultant hereby agrees to provide services, as requested by Mallinckrodt, concerning technical and business matters relative to the Consulting Field as further outlined in Attachment A to this Agreement (such designated services referred to collectively as "Consulting Tasks").
- 1.2. Consultant will utilize the highest degree of skill and expertise in order professionally to accomplish the Consulting Tasks in a timely fashion, and in compliance with all statutes, regulations and industry standards.
- 1.3. The parties agree that the compensation provided hereunder has been established pursuant to arms length negotiations between the parties and is consistent with the fair market value of the services provided by Consultant under this Agreement and will not be based upon the volume or value of any business generated between Consultant and Mallinckrodt with respect to Mallinckrodt products.
- 1.4. Nothing herein shall be construed to require Consultant to purchase, order, prescribe or arrange for the purchase, order, recommendation or prescription of any products manufactured and/or marketed by Mallinckrodt.

### 2. Time, Materials and Facilities; Research Records.

- 2.1. Except where the nature of the Consulting Tasks requires that they be performed at specific times, Consultant is free to choose the specific times at which work will be performed.
- 2.2. Consultant represents and warrants that Consultant will:
  - a. perform his/her obligations hereunder solely on Consultant's own time and solely with supplies and equipment provided by Mallinckrodt or Consultant (but not by any third party), and

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10



- b. perform work only at Mallinckrodt's facilities or at Consultant's facilities (but not at any third party facilities unless Mallinckrodt consents to the use of such facilities). If Consultant is required to perform services at Mallinckrodt, then Consultant agrees at all times to abide by any and all health and safety regulations applicable to any such facilities.

- 2.3. Consultant shall maintain such records, research notes, data and other materials as may be necessary to reflect properly all work done and results achieved in performing this Agreement. All such material shall become Protected Information, as that term is defined in Section 7, and therefore Mallinckrodt's property.

### 3. Term and Termination.

- 3.1. Term. This Agreement shall commence on the Effective Date and remain effective for a twelve (12)-month period thereafter (the "Term"), unless the Agreement is extended by mutual written consent of the parties or terminated earlier.

- 3.2. Termination.

- a. This Agreement may be terminated by either party effective upon thirty (30) days' written notice to the other party.
- b. On termination hereof, or earlier on Mallinckrodt's reasonable request, Consultant shall deliver to Mallinckrodt all materials produced under Section 2.3, and all physical property and documents or other media (including copies) that contain Protected Information, as that term is defined in Section 7.

- 3.3. Survival. The obligations of Consultant set forth in Section 7 hereof shall survive termination or expiration of this Agreement.

### 4. Compensation.

- 4.1. In return for the performance of the Consulting Tasks during the Term, Mallinckrodt will pay Consultant as specifically outlined in Attachment A herein. When appropriate for the work described in Attachment A, Consultant shall invoice Mallinckrodt in one-quarter (¼) hour increments and provide Mallinckrodt with reasonably detailed time entries describing the work performed during said time, for whom said work was performed and the date on which the work was performed.
- 4.2. Mallinckrodt shall pay the uncontested amounts of any invoice, including reimbursement for travel costs and expenses incurred in accordance with Section 5 below, within sixty (60) days of receipt of Consultant's invoice by Mallinckrodt.
- 4.3. Mallinckrodt shall make all checks payable to Consultant at the address provided in Section 8. Mallinckrodt reserves the right to review Consultant's billing and withhold payments for services rendered and expenses incurred outside the scope of this Agreement.

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10



5. Travel and Expenses.

- 5.1. Upon reasonable request by Mallinckrodt, Consultant shall travel to appropriate locations (such as Mallinckrodt facilities, clinical sites, customer locations or vendor facilities) to perform the Consulting Tasks (where the nature of such tasks so requires).
- 5.2. Mallinckrodt shall reimburse Consultant for his/her reasonable and documented out-of-pocket expenses incurred in performing the Consulting Tasks (including reasonable costs of travel outside Consultant's geographic area, but not including any general office or overhead expenses), provided that Consultant:
  - a. provides Mallinckrodt with an itemized expense report and receipts for all expenses, and
  - b. obtains Mallinckrodt's prior written consent for the incurrence of any out-of-pocket expenses for which Consultant wishes to be reimbursed.
- 5.3. It is understood that travel time shall not be considered to be time spent by Consultant providing Consulting Tasks hereunder.
- 5.4. Reasonable travel expenses shall include, when necessary, coach or economy class airfare unless a flight is intercontinental and exceeding six hours of flight time in which case it shall include business class airfare.

6. Representations and Warranties: Debarment and Exclusion.

- 6.1. Consultant represents and warrants that:
  - a. Consultant is not bound by, and will not enter into, any oral or written agreement with another party that conflicts in any way with Consultant's obligations under this Agreement or any agreement made or to be made in connection herewith,
  - b. Consultant's execution of and performance under this Agreement and such related agreements do not require consent or approval of any person that has not already been obtained, and
  - c. Consultant complies with all applicable rules of Consultant's employer regarding outside professional activities.
- 6.2. Mallinckrodt represents and warrants that the following provisions run to the benefit of, and are enforceable by Consultant and Beth Israel Medical Center ("Beth Israel"):
  - a. Mallinckrodt agrees that it will not use the name Beth Israel Medical Center, or any abbreviation, contraction or simulation thereof, in any publicity, advertising or promotional material of any nature, without the express prior written consent of Beth Israel.
  - b. Mallinckrodt agrees to indemnify, defend and hold harmless Consultant and Beth Israel, and Beth Israel's directors, officers, employees and agents (hereinafter the "Indemnified Parties"), from and against any and all claims, losses, damages, liabilities, suits, judgments, settlements and expenses howsoever arising (including but not limited to settlement costs and reasonable legal fees) asserted against any of the Indemnified Parties relating directly or indirectly to the services performed by Consultant under or in connection with this Agreement. This provision shall survive the termination of this Agreement.
  - c. Mallinckrodt shall provide and maintain at its own expense during this Agreement the following insurance coverages with such insurers as shall be acceptable to Beth Israel in

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10





minimum limits of \$1 million per occurrence and \$3 million in the aggregate: professional liability, comprehensive general liability, including products liability, contractual liability and errors and omissions. Mallinckrodt shall give Beth Israel thirty (30) days prior written notice of any changes in or cancellation of such insurance.

6.3. Debarment and Exclusion.

- a. Consultant hereby certifies that Consultant has not been debarred under the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a, or sanctioned by a Federal Health Care Program, as defined in 42 U.S.C. § 1320 a-7b(f), including, but not limited to, the federal Medicare or a state Medicaid program, or debarred, suspended, or excluded from any Federal agency or program.
- b. During the term of this Agreement, if Consultant becomes debarred, suspended, excluded, or otherwise sanctioned, or receives notice of such action prior to the conduct of any agreed-upon speaker presentation, then Consultant shall notify Mallinckrodt immediately, and all agreements and commitments regarding any future presentations shall terminate immediately whether or not Mallinckrodt received timely notice.

7. Treatment of Protected Information; Ownership and Inventions.

7.1. "Protected Information" consists of:

- a. information that Mallinckrodt considers to be proprietary and/or confidential and which was previously or is hereafter disclosed or made available to Consultant by Mallinckrodt, including information relating to Mallinckrodt or its business that becomes available to Consultant due to Consultant's access to Mallinckrodt's property or products,
- b. information that was or is created, developed, conceived, reduced to practice or discovered by Consultant (alone or jointly with others) using any other Protected Information or any property or materials supplied to Consultant by Mallinckrodt,
- c. information that is within Consultant's prior knowledge based on his/her understanding of or his/her historical association with Mallinckrodt or its affiliates, and
- d. proprietary and confidential information of a third party received by Mallinckrodt under obligation of confidentiality and disclosed to Consultant.

7.2. Protected Information shall comprise any and all types of information, including, but not limited to:

- a. inventions, discoveries, developments, improvements, trade secrets, know-how, ideas, techniques, designs, processes, formulae, data and software, the use of concentrates and the technical advantages developed therefrom (collectively, "Inventions"),
- b. plans for research, development, new products, marketing and selling,
- c. budgeting and financial information,
- d. production and sales information including prices, costs, quantities and information about suppliers and customers, and
- e. information about business relationships.

7.3. During the existence of this Agreement and at all times thereafter, Consultant shall:

- a. hold Protected Information in strictest confidence,

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10



- b. not disclose Protected Information to any third party without written consent of Mallinckrodt,
- c. take all reasonable possible steps to safeguard Protected Information, and
- d. not use Protected Information for any purpose other than performing the Consulting Tasks for Mallinckrodt under this Consulting Agreement.

7.4. If Consultant has any employees or consultants, then Consultant agrees to limit disclosure of Protected Information to only those employees or consultants of Consultant with a need to know the information and to secure the written agreement of all such employees and consultants to abide by the provisions of this Agreement. Consultant acknowledges that it is fully responsible and liable for any disclosure of Protected Information by its employees or consultants in violation of the terms of this Agreement.

7.5. Mallinckrodt shall be the sole owner of all Protected Information, and it is understood that any intellectual property of any nature developed, conceived or reduced to practice by Consultant during the existence of this Agreement or thereafter, in either case to the extent derived from Consultant's use or understanding of Protected Information shall be the property of Mallinckrodt.

8. Notices.

8.1. Any notice required or permitted to be given under this Agreement shall be in writing, and shall be deemed to have been given when delivered personally or sent by registered or certified mail, postage prepaid to the following addresses:

8.2. If to Mallinckrodt:

Medical Affairs  
Attn: Art Morelli  
Covidien  
675 McDonnell Boulevard  
Hazelwood, MO 63042  
314-654-6583

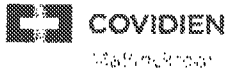
*With a copy to --*

Brian Elsbernd  
Senior Compliance Counsel  
Covidien  
675 McDonnell Boulevard, 10-4-S  
Hazelwood, MO 63042  
(314) 654-3168

8.3. If to Consultant:

Dr. Russell Portenoy, MD  
First Ave. at 16<sup>th</sup> Street  
New York, NY 10003  
[rporten@chpnet.org](mailto:rporten@chpnet.org)

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10




9. Miscellaneous.


- 9.1. Independent Contractor. Consultant shall at all times act as an independent contractor and not as an employee of Mallinckrodt. Accordingly, Consultant understands that Mallinckrodt will not pay or withhold from payments to Consultant under this Consulting Agreement any social security, state unemployment or disability insurance premiums, state or federal income taxes, or other taxes.
- 9.2. Taxpayer Identification Number. The Consultant agrees to provide a signed and complete IRS Form W-9 upon request and prior to any payments being issued.
- 9.3. Compliance with Laws. In accordance with Section 9.8, below, Consultant will at all times during the Term comply with all statutes, rules and regulations that may be applicable to Consultant's performance hereunder.
- 9.4. Entire Agreement; Amendments. This Agreement constitutes the entire agreement between the parties relating to the subject matter hereof, and supersedes any and all prior agreements, discussions or courses of dealing. Except as expressly provided herein, this Agreement shall not be amended except by written agreement executed by authorized representatives of both the parties.
- 9.5. Severability. If any term, covenant or condition of this Agreement shall for any reason be held unenforceable by a court of competent jurisdiction, then the rest of this Agreement shall remain in full force and shall in no way be affected or impaired and, if and to the extent it is possible, the parties shall replace the unenforceable or invalid provision with one that is valid and enforceable and that is as close in its intent and effect as possible to the original provision.
- 9.6. Assignment. This Agreement is not assignable by either party without the written consent of the other party, except that, without the consent of Consultant, Mallinckrodt may assign this Agreement to any affiliate of Mallinckrodt, now or hereafter existing, or to a purchaser of all or substantially all of Mallinckrodt's business to which this Agreement relates.
- 9.7. No Waiver. Either party's failure to require the other party to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement.
- 9.8. Governing Law. This Agreement shall be governed and construed under New York law, excluding its choice of law rules.
- 9.9. Limitation of Liability. In no event shall Mallinckrodt be liable to Consultant for punitive, indirect, incidental or consequential damages, including without limitation, liability for loss of use, loss of profits, loss of product or business interruption.

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10



IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the Effective Date.

CONSULTANT  
By:   
Name: Dr. Russell Portenoy, MD

MALLINCKRODT, INC.  
By:   
Name: Herbert R. Neuman, M.D., M.B.A.  
Title: Chief Medical Officer

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10

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FEB-24-2010 11:25

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Attachment A

This Attachment A to the Consulting Agreement (the "Agreement") of February 5, 2010 ("Effective Date") by and between Dr. Russell Portenoy, MD with an address at First Ave. at 16<sup>th</sup> Street, New York, NY 10003 ("Consultant") and Mallinckrodt Inc., a Delaware corporation with offices located at 675 McDonnell Boulevard, Hazelwood, Missouri 63042 ("Mallinckrodt") is intended to further outline the mutual agreement of the parties concerning the Consulting Tasks to be performed by the Consultant at the direction of Mallinckrodt, specifically:

1. Consultant will serve as the Chair of the Safe Use Alliance Advisory Board (the "Board") planned to occur on February 26, 2010 in New York City, New York. The Board will provide input and guidance based on the Member's experience and knowledge with pain and addiction medicine as well as experience in setting up similar educational programs. The Board will further advise Mallinckrodt on the development of educational tools and make recommendations on risk mitigation tools. It is anticipated that this meeting will be for approximately six to eight hours with participants expected to have fully reviewed and understood any notes or materials provided to them in advance in order to facilitate detailed and meaningful discussion. As Chair, the Consultant will also be involved in the formulation of the agenda and will review any preparatory materials before distribution. For this meeting, and its preparation and documentation described herein, the Consultant shall be paid \$3,500 plus reasonable expenses.
2. Consultant will also provide, based upon his availability, input and guidance to Mallinckrodt's Patient and Product Safety Department outside of the planning and execution for meetings of the Board. This work will be compensated at the rate of \$450 per hour. Payment of invoices for this work will not be completed without suitable documentation of the work performed, when it was performed, and identifying any Mallinckrodt employee who requests it.

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10



## EDUCATIONAL PRECEPTORSHIP AGREEMENT

This PRECEPTORSHIP AGREEMENT (the “Agreement”) is made as of November 15, 2010 (“Effective Date”) by and between Department of Pain Medicine and Palliative Care, Beth Israel Medical Center with an address at First Avenue at 16th Street, New York, New York, 10003 (“Preceptor”) and Mallinckrodt Inc., a Delaware corporation and a Covidien company with offices located at 675 McDonnell Boulevard, Hazelwood, MO 63042 (“Mallinckrodt”).

WHEREAS, Preceptor possesses expertise in the areas of Pain Management and Palliative Care (“Consulting Field”), and wishes to make its expertise and efforts in the Consulting Field available to Mallinckrodt, and

WHEREAS, Mallinckrodt desires to engage the services of Preceptor to provide a Preceptorship, as defined herein, within the Consulting Field to its employee(s) on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of these premises and the promises set forth herein, Mallinckrodt and Preceptor hereby agree as follows:

1. Engagement of Preceptor.

- 1.1. Mallinckrodt hereby engages Preceptor, and Preceptor hereby agrees to provide a Preceptorship, as requested by Mallinckrodt, concerning the Consulting Field as further outlined in Attachment A to this Agreement.
- 1.2. The parties agree that the compensation provided hereunder has been established pursuant to arms length negotiations between the parties and is consistent with the fair market value of the services provided by Preceptor under this Agreement and will not be based upon the volume or value of any business generated between Preceptor and Mallinckrodt with respect to Mallinckrodt products.
- 1.3. Nothing herein shall be construed to require Preceptor to purchase, order, prescribe or arrange for the purchase, order, recommendation or prescription of any products manufactured and/or marketed by Mallinckrodt.

2. Time, Materials and Facilities.

- 2.1. The Preceptorship will be conducted at a mutually agreed upon time at the clinical location of the Preceptor.
- 2.2. Preceptor represents and warrants that Preceptor will:
  - a. perform its obligations hereunder solely through Preceptor's employees, and
  - b. perform work at Preceptor's facilities (but not at any third party facilities unless the Preceptor obtains the written consent to the use of such facilities).

Preceptorship Beth Israel BDE  
1-06-11





3. Term and Termination.

- 3.1. Term. This Agreement shall only last until the completion of the work outlined in Attachment A though the terms of this Agreement may be adopted by subsequent agreement of the parties but for no reason shall this be longer than one year from the date of execution
- 3.2. Termination. Either party may cancel this Agreement with written notice to the other within three days of the scheduled activity.

4. Compensation.

- 4.1. In return for the performance of the Consulting Tasks during the Term, Mallinckrodt will pay Preceptor as specifically outlined in Attachment A herein. Preceptor shall invoice Mallinckrodt promptly upon completion of the work. Payment shall be due within 45 days of the presentation of an invoice by Preceptor or the completion of the work, whichever is later.
- 4.2. Mallinckrodt shall make all checks payable to Preceptor at the address provided in Section 8. Mallinckrodt reserves the right to review Preceptor's billing and withhold payments for services rendered and expenses incurred outside the scope of this Agreement.

5. Representations and Warranties; Debarment and Exclusion.

- 5.1. Preceptor represents and warrants that Preceptor's execution of and performance under this Agreement and such related agreements do not require consent or approval of any person that has not already been obtained.
- 5.2. Mallinckrodt represents and warrants that the following provisions run to the benefit of, and are enforceable by Consultant and Beth Israel Medical Center ("Beth Israel"):
  - a. Mallinckrodt agrees that it will not use the name Beth Israel Medical Center, or any abbreviation, contraction or simulation thereof, in any publicity, advertising or promotional material of any nature, without the express prior written consent of Beth Israel.
  - b. Mallinckrodt agrees to indemnify, defend and hold harmless Consultant and Beth Israel, and Beth Israel's directors, officers, employees and agents (hereinafter the "Indemnified Parties"), from and against any and all claims, losses, damages, liabilities, suits, judgments, settlements and expenses howsoever arising (including but not limited to settlement costs and reasonable legal fees) asserted against any of the Indemnified Parties relating directly or indirectly to the services performed by Consultant under or in connection with this Agreement. This provision shall survive the termination of this Agreement.
  - c. Mallinckrodt shall provide and maintain at its own expense during this Agreement the following insurance coverages with such insurers as shall be acceptable to Beth Israel in minimum limits of \$1 million per occurrence and \$3 million in the aggregate: professional liability, comprehensive general liability, including products liability, contractual liability

Preceptorship Beth Israel BDE  
1-06-11



and errors and omissions. Mallinckrodt shall give Beth Israel thirty (30) days prior written notice of any changes in or cancellation of such insurance.

5.3. Debarment and Exclusion.

- a. Preceptor hereby certifies that Preceptor has not been debarred under the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a, or sanctioned by a Federal Health Care Program, as defined in 42 U.S.C. § 1320 a-7b(f), including, but not limited to, the federal Medicare or a state Medicaid program, or debarred, suspended, or excluded from any Federal agency or program.
- b. During the term of this Agreement, if Preceptor becomes debarred, suspended, excluded, or otherwise sanctioned, or receives notice of such action prior to the conduct of any agreed-upon speaker presentation, then Preceptor shall notify Mallinckrodt immediately, and all agreements and commitments regarding any future presentations shall terminate immediately whether or not Mallinckrodt received timely notice.

6. Treatment of Protected Information.

- 6.1. "Protected Information" consists of "Protected Health Information" or PHI, as that term is defined in the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations. At all times, Mallinckrodt represents that its employees have been trained on how to handle PHI and to safeguard all PHI from release or disclosure.
- 6.2. Mallinckrodt agrees to review and make any written commitments necessary to accommodate the handling and protection of PHI as long as the Preceptor provides those written commitments for review by Mallinckrodt's Legal staff at least seven days prior to the scheduled date of a preceptorship. In the event that the written commitments requested are determined by Mallinckrodt to be unacceptable, then the Agreement can be terminated prior to the Preceptorship by either party.

7. Notices.

- 7.1. Any notice required or permitted to be given under this Agreement shall be in writing, and shall be deemed to have been given when delivered personally or sent by registered or certified mail, postage prepaid to the following addresses:
- 7.2. If to Mallinckrodt:

Brian Elsbernd  
Senior Compliance Counsel  
Covidien  
675 McDonnell Boulevard, 10-4-S  
Hazelwood, MO 63042

Preceptorship Beth Israel BDE  
1-06-11



(314) 654-3168

7.3. If to Preceptor:

Department of Pain Medicine and Palliative Care  
Beth Israel Medical Center  
First Avenue at 16<sup>th</sup> Street  
New York, NY 10003  
Attn: Russell K. Portenoy, MD  
212-844-1505

Miscellaneous.

- 7.4. Independent Contractor. Preceptor shall at all times act as an independent contractor and not as an employee of Mallinckrodt. Accordingly, Preceptor understands that Mallinckrodt will not pay or withhold from payments to Preceptor under this Consulting Agreement any social security, state unemployment or disability insurance premiums, state or federal income taxes, or other taxes.
- 7.5. Taxpayer Identification Number. The Preceptor agrees to provide a signed and complete IRS Form W-9 upon request and prior to any payments being issued.
- 7.6. Compliance with Laws. Preceptor will at all times during the Term comply with all statutes, rules and regulations that may be applicable to Preceptor's performance hereunder.
- 7.7. Entire Agreement; Amendments. This Agreement constitutes the entire agreement between the parties relating to the subject matter hereof, and supersedes any and all prior agreements, discussions or courses of dealing. Except as expressly provided herein, this Agreement shall not be amended except by written agreement executed by authorized representatives of both the parties.
- 7.8. Severability. If any term, covenant or condition of this Agreement shall for any reason be held unenforceable by a court of competent jurisdiction, then the rest of this Agreement shall remain in full force and shall in no way be affected or impaired and, if and to the extent it is possible, the parties shall replace the unenforceable or invalid provision with one that is valid and enforceable and that is as close in its intent and effect as possible to the original provision.
- 7.9. Assignment. This Agreement is not assignable by either party without the written consent of the other party, except that, without the consent of Preceptor, Mallinckrodt may assign this Agreement to any affiliate of Mallinckrodt, now or hereafter existing, or to a purchaser of all or substantially all of Mallinckrodt's business to which this Agreement relates.
- 7.10. No Waiver. Either party's failure to require the other party to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement.

Preceptorship Beth Israel BDE  
1-06-11

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- 7.11. Governing Law. This Agreement shall be governed and construed under Missouri law, excluding its choice of law rules. WITH RESPECT TO ANY DISPUTES ARISING UNDER THIS AGREEMENT, THE PARTIES IRREVOCABLY CONSENT TO THE EXCLUSIVE JURISDICTION OF THE CIRCUIT COURT OF ST. LOUIS COUNTY, MISSOURI AND AGREE THAT SUCH DISPUTES SHALL BE ADDRESSED ONLY BY THAT COURT.
- 7.12. Disclosure of Payments. Preceptor understands, and acknowledges, that Covidien may, when required by law, provide reports of payments and activities covered by this Agreement to governmental agencies and that those reports may subsequently be made a part of the public record or otherwise published.
- 7.13. Limitation of Liability. In no event shall Mallinckrodt be liable to Preceptor for punitive, indirect, incidental or consequential damages, including without limitation, liability for loss of use, loss of profits, loss of product or business interruption.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the Effective Date.

PRECEPTOR

MALLINCKRODT, INC.

By:

A handwritten signature in black ink, appearing to read 'R. Portenoy', is written over a horizontal dotted line.

Name: Russell Portenoy, MD  
Title: Chair, Department of Pain Medicine and Palliative  
Care

By:

Name: Herbert R. Neuman, M.D., M.B.A.  
Title: Chief Medical Officer



Attachment A

This Attachment A to the Consulting Agreement (the "Agreement") of November 15, 2010 ("Effective Date") by and between Department of Pain Medicine and Palliative Care, Beth Israel Medical Center with an address at First Avenue at 16th Street, New York, New York, 10003 ("Preceptor") and Mallinckrodt Inc., a Delaware corporation with offices located at 675 McDonnell Boulevard, Hazelwood, Missouri 63042 ("Mallinckrodt") is intended to further outline the mutual agreement of the parties concerning the Preceptorship to be performed by the Preceptor at the request of Mallinckrodt, specifically:

1. On a date mutually agreed upon by Mallinckrodt and Preceptor in writing during January 2011, Preceptor will conduct a one day preceptorship with Covidien Medical Science Liaisons (MSLs) or other Medical Affairs representatives at it facilities in New York City, New York. The preceptorship will last for at least six hours, and no more than eight hours, during which the Preceptor will provide advanced clinical education to the MSL by educating them on all aspects of clinical practice including, but not limited to: 1) Patient assessment/evaluation, 2) Diagnosis and supportive testing/imaging, 3) Patient and Disease Management, 4) Treatment Options, 5) Health outcomes, 6) Formulary and Access discussions, 7) Other aspects of patient care.
2. For the work outlined in item 1., above, the Preceptor shall be paid a total of \$8,000 (eight thousand dollars) for the anticipated up to 8 Covidien MSLs attending. Such payment will be made upon presentation of an invoice by the Preceptor to Mallinckrodt in accordance with the terms of this Agreement.

Preceptorship Beth Israel BDE  
1-06-11

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Legal Division  
Trademark Department  
Pfizer Inc.  
150 East 42<sup>nd</sup> Street  
New York, NY 10017-5755  
Fax: 212-573-2273

Jane Ungaro  
Senior Corporate Counsel  
Telephone: 212 733-5211  
Fax: 212 573 2273

October 23, 2008

Russell K. Portenoy, MD  
Chairman, Department of Pain and Palliative Care,  
Beth Israel  
First Avenue at 16th Street  
New York, NY 10003

Re: OR-SDS

Dear Dr. Portenoy,

Thank you for granting Pfizer Inc. ("Pfizer") permission to adapt the Memorial Symptom Assessment Scale in connection with the creation of the OR-SDS (Opioid Related Symptom Distress Scale). We write to confirm that Pfizer will use the following acknowledgement in its copyright statement: Adapted with permission from the Memorial Symptom Assessment Scale by Portenoy, et al.

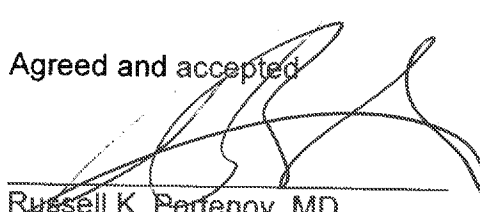
Please confirm that you agree with our understanding by signing below and returning the signed copy of this letter to my attention via email (jane.ungaro@pfizer.com), fax (212-573-2273) or regular mail.

Thank you again for your permission.

Sincerely,

  
Jane Ungaro

Agreed and accepted

  
\_\_\_\_\_  
Russell K. Portenoy, MD

Date: 10/23/08

CONFIDENTIAL

RP\_000538





Research and Development  
4000 CentreGreen Way, Suite 300  
Cary, North Carolina 27513  
Telephone: (919) 653-7001

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October 28, 2010

*Via Federal Express*

*Re: Consulting Agreement*

Dear Dr. Portenoy:

Attached please find duplicate originals of the Consulting Agreement. Please have both Agreements signed, return one to me in the enclosed Federal Express envelope and keep the other for your files. If you have any questions or need any additional assistance, please feel free to contact me directly. I appreciate your time and assistance in this matter and look forward to working with you again. Thank you.

Sincerely,

A handwritten signature in cursive script, appearing to read "D Marsulá".

Donna-Jean Marsulá  
Contract Administrator

Enclosures



## CONSULTING AGREEMENT

This CONSULTING AGREEMENT (the "Agreement") is made as of February 5, 2010 ("Effective Date") by and between Dr. Russell Portenoy, MD with an address at First Ave. at 16<sup>th</sup> Street, New York, NY 10003 ("Consultant") and Mallinckrodt Inc., a Delaware corporation and a Covidien company with offices located at 675 McDonnell Boulevard, Hazelwood, MO 63042 ("Mallinckrodt").

WHEREAS, Consultant possesses expertise in the areas of Pain and Addiction Medicine ("Consulting Field"), and wishes to make his/her expertise and efforts in the Consulting Field available to Mallinckrodt, and

WHEREAS, Mallinckrodt desires to engage the services of Consultant for the performance of certain specific tasks or projects to be specified by Mallinckrodt that are related to the Consulting Field on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of these premises and the promises set forth herein, Mallinckrodt and Consultant hereby agree as follows:

1. Engagement of Consultant.

- 1.1. Mallinckrodt hereby engages Consultant, and Consultant hereby agrees to provide services, as requested by Mallinckrodt, concerning technical and business matters relative to the Consulting Field as further outlined in Attachment A to this Agreement (such designated services referred to collectively as "Consulting Tasks").
- 1.2. Consultant will utilize the highest degree of skill and expertise in order professionally to accomplish the Consulting Tasks in a timely fashion, and in compliance with all statutes, regulations and industry standards.
- 1.3. The parties agree that the compensation provided hereunder has been established pursuant to arms length negotiations between the parties and is consistent with the fair market value of the services provided by Consultant under this Agreement and will not be based upon the volume or value of any business generated between Consultant and Mallinckrodt with respect to Mallinckrodt products.
- 1.4. Nothing herein shall be construed to require Consultant to purchase, order, prescribe or arrange for the purchase, order, recommendation or prescription of any products manufactured and/or marketed by Mallinckrodt.

2. Time, Materials and Facilities; Research Records.

- 2.1. Except where the nature of the Consulting Tasks requires that they be performed at specific times, Consultant is free to choose the specific times at which work will be performed.
- 2.2. Consultant represents and warrants that Consultant will:
  - a. perform his/her obligations hereunder solely on Consultant's own time and solely with supplies and equipment provided by Mallinckrodt or Consultant (but not by any third party), and

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10





5. Travel and Expenses.

- 5.1. Upon reasonable request by Mallinckrodt, Consultant shall travel to appropriate locations (such as Mallinckrodt facilities, clinical sites, customer locations or vendor facilities) to perform the Consulting Tasks (where the nature of such tasks so requires).
- 5.2. Mallinckrodt shall reimburse Consultant for his/her reasonable and documented out-of-pocket expenses incurred in performing the Consulting Tasks (including reasonable costs of travel outside Consultant's geographic area, but not including any general office or overhead expenses), provided that Consultant:
  - a. provides Mallinckrodt with an itemized expense report and receipts for all expenses, and
  - b. obtains Mallinckrodt's prior written consent for the incurrence of any out-of-pocket expenses for which Consultant wishes to be reimbursed.
- 5.3. It is understood that travel time shall not be considered to be time spent by Consultant providing Consulting Tasks hereunder.
- 5.4. Reasonable travel expenses shall include, when necessary, coach or economy class airfare unless a flight is intercontinental and exceeding six hours of flight time in which case it shall include business class airfare.

6. Representations and Warranties; Debarment and Exclusion.

- 6.1. Consultant represents and warrants that:
  - a. Consultant is not bound by, and will not enter into, any oral or written agreement with another party that conflicts in any way with Consultant's obligations under this Agreement or any agreement made or to be made in connection herewith,
  - b. Consultant's execution of and performance under this Agreement and such related agreements do not require consent or approval of any person that has not already been obtained, and
  - c. Consultant complies with all applicable rules of Consultant's employer regarding outside professional activities.
- 6.2. Mallinckrodt represents and warrants that the following provisions run to the benefit of, and are enforceable by Consultant and Beth Israel Medical Center ("Beth Israel"):
  - a. Mallinckrodt agrees that it will not use the name Beth Israel Medical Center, or any abbreviation, contraction or simulation thereof, in any publicity, advertising or promotional material of any nature, without the express prior written consent of Beth Israel.
  - b. Mallinckrodt agrees to indemnify, defend and hold harmless Consultant and Beth Israel, and Beth Israel's directors, officers, employees and agents (hereinafter the "Indemnified Parties"), from and against any and all claims, losses, damages, liabilities, suits, judgments, settlements and expenses howsoever arising (including but not limited to settlement costs and reasonable legal fees) asserted against any of the Indemnified Parties relating directly or indirectly to the services performed by Consultant under or in connection with this Agreement. This provision shall survive the termination of this Agreement.
  - c. Mallinckrodt shall provide and maintain at its own expense during this Agreement the following insurance coverages with such insurers as shall be acceptable to Beth Israel in

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10



minimum limits of \$1 million per occurrence and \$3 million in the aggregate: professional liability, comprehensive general liability, including products liability, contractual liability and errors and omissions. Mallinckrodt shall give Beth Israel thirty (30) days prior written notice of any changes in or cancellation of such insurance.

6.3. Debarment and Exclusion.

- a. Consultant hereby certifies that Consultant has not been debarred under the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a, or sanctioned by a Federal Health Care Program, as defined in 42 U.S.C. § 1320 a-7b(f), including, but not limited to, the federal Medicare or a state Medicaid program, or debarred, suspended, or excluded from any Federal agency or program.
- b. During the term of this Agreement, if Consultant becomes debarred, suspended, excluded, or otherwise sanctioned, or receives notice of such action prior to the conduct of any agreed-upon speaker presentation, then Consultant shall notify Mallinckrodt immediately, and all agreements and commitments regarding any future presentations shall terminate immediately whether or not Mallinckrodt received timely notice.

7. Treatment of Protected Information; Ownership and Inventions.

7.1. "Protected Information" consists of:

- a. information that Mallinckrodt considers to be proprietary and/or confidential and which was previously or is hereafter disclosed or made available to Consultant by Mallinckrodt, including information relating to Mallinckrodt or its business that becomes available to Consultant due to Consultant's access to Mallinckrodt's property or products,
- b. information that was or is created, developed, conceived, reduced to practice or discovered by Consultant (alone or jointly with others) using any other Protected Information or any property or materials supplied to Consultant by Mallinckrodt,
- c. information that is within Consultant's prior knowledge based on his/her understanding of or his/her historical association with Mallinckrodt or its affiliates, and
- d. proprietary and confidential information of a third party received by Mallinckrodt under obligation of confidentiality and disclosed to Consultant.

7.2. Protected Information shall comprise any and all types of information, including, but not limited to:

- a. inventions, discoveries, developments, improvements, trade secrets, know-how, ideas, techniques, designs, processes, formulae, data and software, the use of concentrates and the technical advantages developed therefrom (collectively, "Inventions"),
- b. plans for research, development, new products, marketing and selling,
- c. budgeting and financial information,
- d. production and sales information including prices, costs, quantities and information about suppliers and customers, and
- e. information about business relationships.

7.3. During the existence of this Agreement and at all times thereafter, Consultant shall:

- a. hold Protected Information in strictest confidence,

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10



- b. not disclose Protected Information to any third party without written consent of Mallinckrodt,
- c. take all reasonable possible steps to safeguard Protected Information, and
- d. not use Protected Information for any purpose other than performing the Consulting Tasks for Mallinckrodt under this Consulting Agreement.

7.4. If Consultant has any employees or consultants, then Consultant agrees to limit disclosure of Protected Information to only those employees or consultants of Consultant with a need to know the information and to secure the written agreement of all such employees and consultants to abide by the provisions of this Agreement. Consultant acknowledges that it is fully responsible and liable for any disclosure of Protected Information by its employees or consultants in violation of the terms of this Agreement.

7.5. Mallinckrodt shall be the sole owner of all Protected Information, and it is understood that any intellectual property of any nature developed, conceived or reduced to practice by Consultant during the existence of this Agreement or thereafter, in either case to the extent derived from Consultant's use or understanding of Protected Information shall be the property of Mallinckrodt.

8. Notices.

8.1. Any notice required or permitted to be given under this Agreement shall be in writing, and shall be deemed to have been given when delivered personally or sent by registered or certified mail, postage prepaid to the following addresses:

8.2. If to Mallinckrodt:

Medical Affairs  
Attn: Art Morelli  
Covidien  
675 McDonnell Boulevard  
Hazelwood, MO 63042  
314-654-6583

*With a copy to –*

Brian Elsbernd  
Senior Compliance Counsel  
Covidien  
675 McDonnell Boulevard, 10-4-S  
Hazelwood, MO 63042  
(314) 654-3168

8.3. If to Consultant:

Dr. Russell Portenoy, MD  
First Ave. at 16<sup>th</sup> Street  
New York, NY 10003  
[rportenoy@chpnet.org](mailto:rportenoy@chpnet.org)

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10





9. Miscellaneous.

- 9.1. Independent Contractor. Consultant shall at all times act as an independent contractor and not as an employee of Mallinckrodt. Accordingly, Consultant understands that Mallinckrodt will not pay or withhold from payments to Consultant under this Consulting Agreement any social security, state unemployment or disability insurance premiums, state or federal income taxes, or other taxes.
- 9.2. Taxpayer Identification Number. The Consultant agrees to provide a signed and complete IRS Form W-9 upon request and prior to any payments being issued.
- 9.3. Compliance with Laws. In accordance with Section 9.8, below, Consultant will at all times during the Term comply with all statutes, rules and regulations that may be applicable to Consultant's performance hereunder.
- 9.4. Entire Agreement; Amendments. This Agreement constitutes the entire agreement between the parties relating to the subject matter hereof, and supersedes any and all prior agreements, discussions or courses of dealing. Except as expressly provided herein, this Agreement shall not be amended except by written agreement executed by authorized representatives of both the parties.
- 9.5. Severability. If any term, covenant or condition of this Agreement shall for any reason be held unenforceable by a court of competent jurisdiction, then the rest of this Agreement shall remain in full force and shall in no way be affected or impaired and, if and to the extent it is possible, the parties shall replace the unenforceable or invalid provision with one that is valid and enforceable and that is as close in its intent and effect as possible to the original provision.
- 9.6. Assignment. This Agreement is not assignable by either party without the written consent of the other party, except that, without the consent of Consultant, Mallinckrodt may assign this Agreement to any affiliate of Mallinckrodt, now or hereafter existing, or to a purchaser of all or substantially all of Mallinckrodt's business to which this Agreement relates.
- 9.7. No Waiver. Either party's failure to require the other party to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement.
- 9.8. Governing Law. This Agreement shall be governed and construed under New York law, excluding its choice of law rules.
- 9.9. Limitation of Liability. In no event shall Mallinckrodt be liable to Consultant for punitive, indirect, incidental or consequential damages, including without limitation, liability for loss of use, loss of profits, loss of product or business interruption.



IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the Effective Date.

CONSULTANT

MALLINCKRODT, INC.

By:   
Name: Dr. Russell Portenoy, MD

By: \_\_\_\_\_  
Name: Herbert R. Neuman, M.D., M.B.A.  
Title: Chief Medical Officer

Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10

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Attachment A

This Attachment A to the Consulting Agreement (the "Agreement") of February 5, 2010 ("Effective Date") by and between Dr. Russell Portenoy, MD with an address at First Ave. at 16<sup>th</sup> Street, New York, NY 10003 ("Consultant") and Mallinckrodt Inc., a Delaware corporation with offices located at 675 McDonnell Boulevard, Hazelwood, Missouri 63042 ("Mallinckrodt") is intended to further outline the mutual agreement of the parties concerning the Consulting Tasks to be performed by the Consultant at the direction of Mallinckrodt, specifically:

1. Consultant will serve as the Chair of the Safe Use Alliance Advisory Board (the "Board") planned to occur on February 26, 2010 in New York City, New York. The Board will provide input and guidance based on the Member's experience and knowledge with pain and addiction medicine as well as experience in setting up similar educational programs. The Board will further advise Mallinckrodt on the development of educational tools and make recommendations on risk mitigation tools. It is anticipated that this meeting will be for approximately six to eight hours with participants expected to have fully reviewed and understood any notes or materials provided to them in advance in order to facilitate detailed and meaningful discussion. As Chair, the Consultant will also be involved in the formulation of the agenda and will review any preparatory materials before distribution. For this meeting, and its preparation and documentation described herein, the Consultant shall be paid \$3,500 plus reasonable expenses.
2. Consultant will also provide, based upon his availability, input and guidance to Mallinckrodt's Patient and Product Safety Department outside of the planning and execution for meetings of the Board. This work will be compensated at the rate of \$450 per hour. Payment of invoices for this work will not be completed without suitable documentation of the work performed, when it was performed, and identifying any Mallinckrodt employee who requests it.

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Safe Use Alliance Ad Board Portenoy Chair BDE 2-22-10

DEPARTMENT OF PAIN MEDICINE AND PALLIATIVE CARE  
Beth Israel Medical Center  
First Avenue at 16<sup>th</sup> Street  
New York, NY 10003  
Phone - (212) 844 -1505  
Fax - (212) 844 -1503

# Fax

**To:** Desiree Hollandsworth

**From:** Dr. Portenoy

**Fax:** 267-893-6915

**Pages:**

**Phone:**

**Date:** 2/23/10

**Re:**

**CC:**

☐ **Urgent**    ☐ **For Review**    ☐ **Please Comment**    ☐ **Please Reply**    ☐ **Please Recycle**

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## CONSULTANT AGREEMENT INSTRUCTIONS

- 1) Initial one copy; blue ink is preferred
- 2) Fax one to Synchrony Healthcare Communications

Attention: Desirée Hollandsworth

Fax 267-893-6915

- 3) Return initialed original to Brian Elsbernd in the Federal Express Envelope provided. A pre-addressed label has been prepared for you.

Brian Elsbernd  
Chief Compliance Officer  
Senior Compliance Counsel  
Covidien/Mallinckrodt  
Imaging Solutions and Pharmaceuticals  
675 McDonnell Blvd.  
Hazelwood, MO 63042  
o) 314-654-3168

Thank you

Abstral (fentanyl) sublingual tablets  
Medical Affairs Advisory Board  
March 22, 2011  
Gaylord National Hotel & Convention Center  
National Harbor, Maryland

Dear Dr. Portenoy:

On behalf of Greg Guillory, US Director of Medical Affairs, and Julian Howell, Head of Clinical Development and Medical Affairs, from ProStrakan Inc., I am pleased to invite you to participate in an upcoming Abstral (fentanyl) sublingual tablets Medical Advisory Board. Abstral is an opioid analgesic indicated only for the management of breakthrough pain in cancer patients, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. We are interested in seeking your input on the issues concerning the use of opioids for management of breakthrough cancer pain, and as a means of achieving this objective, we will provide a brief overview of the Abstral development program that will include a description of the Abstral Risk Evaluation and Mitigation Strategy. This background information will serve as a basis for discussions focused on the types of issues and information that need to be disseminated to oncologists and pain specialists.

The meeting will take place on Tuesday, March 22 from 2:00pm – 7:00pm at the Gaylord National Hotel & Convention Center in National Harbor, Maryland prior to the American Academy of Pain Medicine. Arrivals will take place on the afternoon of March 22<sup>nd</sup> and an afternoon snack and dinner will be provided during the meeting.

Please note that the American Academy of Pain Medicine has events that will begin the day after our meeting, beginning on March 23, and for those who are attending the congress, we would be pleased to provide 1-night stay at the Gaylord National Hotel & Convention Center and reimbursement for any extra expenses incurred with travel costs to attend the advisory board meeting. Honorarium of \$1,250 will be provided for your time devoted to working in the meeting.

Complete Healthcare Communications, Inc. (CHC) has been commissioned by ProStrakan, Inc. and is pleased to assist with the logistics for this meeting. Please respond to me via email ([jennifer.kurdziel@chcinc.com](mailto:jennifer.kurdziel@chcinc.com)) or fax (610-358-3636) with the response form provided (attached).

We hope that you are able to join us for this Advisory Board. If you have any questions about this meeting, please do not hesitate to contact me.

Best regards,

*Jen Kurdziel*

Jennifer Kurdziel  
Sr. Project Manager  
Complete Healthcare Communications, Inc.  
One Dickinson Drive  
Chadds Ford, PA 19317  
Phone: 610-358-3600  
Fax: 610-358-3636

*Please respond "No" by 4/1/11*

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## Response Form

Kindly respond by Monday, March 7, 2011.

Please return the form via email ([jennifer.kurdziel@chcinc.com](mailto:jennifer.kurdziel@chcinc.com)) or fax (610-358-3636).

Name: Russell Portenoy, MD

☐ Yes, I am able to attend.

☒ No, I am unable to attend.

If you are able to attend we will send to you a Consultancy Agreement, Confidentiality Agreement and other materials related to the Advisory Board. Please indicate below the Contact Information for communications regarding this Advisory Board.

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Telephone: \_\_\_\_\_

FAX: \_\_\_\_\_

Preferred email address: \_\_\_\_\_

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RP\_000551

**Russell Portenoy, MD**

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**From:** Russell Portenoy, MD  
**Sent:** Monday, July 11, 2011 9:11 AM  
**To:** 'Coplan, Paul'  
**Cc:** Donna Reid; Kaiko, Dr Robert  
**Subject:** RE: Purdue PAB Discussion: request for suggestions on revising REMS Training Blueprint

Dear Paul,

The outline is comprehensive but also redundant in parts and unnecessary in parts. It also doesn't bring together the key messages that I discussed on the phone: universal precautions, risk stratification, compliance monitoring commensurate with risk, and the like. It also appears to unnecessary include what is largely a duplication of the PI's for each drug. Finally, it is not structured in a way that supports pedagogy.

I wouldn't think that a "red pen" taken to the outline by one experienced non-IWG guy (me) would strongly influence the outcome now, particularly since it is so likely that one person's deletion is another person's key point, it may or may not be the groups' desire to have a "key message" component, and the effort to introduce pedagogical principles may or may not be goal.

Nonetheless, I have little doubt that this could be made into a template for a 3-4 hour educational piece. To get there, a process would be needed that allowed broad editing followed by reconstruction of the consensus. I don't know the rules. Maybe the IWG would ask for a volunteer academic group to review it using a Delphi method, or could it go through a review by a professional society group?

If I were asked to participate in a process, I would, and would need a little time to thoughtfully contribute to decisions about what is core, and what is supplemental, and where are the key messages could be derived and presented.

Russ

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**From:** Coplan, Paul [mailto:Paul.Coplan@pharma.com]  
**Sent:** Friday, July 08, 2011 1:36 PM  
**To:** Russell Portenoy, MD  
**Cc:** Donna Reid; Kaiko, Dr Robert  
**Subject:** Purdue PAB Discussion: request for suggestions on revising REMS Training Blueprint

Russ,

Thanks for the productive call yesterday. As discussed, could you please provide suggestions for revising the Blueprint for the Prescriber Training for the Long-acting/Extended-Release Opioid REMS to be shorter yet cover the key points.

Our target is 3-4 hours. The Blueprint is currently about a 10 to 13 hr training. We are using an outline format rather than full-text content to avoid running afoul of ACCME accreditation rules where industry cannot dictate content of CME/CE.

FDA sent us a template to follow when creating the Blueprint for the Prescriber Training, which is contained in Appendix B of the FDA's letter to companies, that is attached for your reference. Whenever possible, we would prefer to follow FDA's outline.

Please provide by COB Tuesday if at all possible. ☺!!

Thanks,  
Paul

**Russell Portenoy, MD**

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**From:** Camp-Font, Nancy [Nancy.Camp-Font@pharma.com]  
**Sent:** Thursday, March 31, 2011 9:17 AM  
**To:** Adam Gorelick; Dr. Candiotti; Dr. Fine; Gudin, Jeffery; Katz, Nathaniel; Dr. Kehlet; Kelley, John; Dr. Kryger; Dr. McCarberg; Miaskowski, Christine; Dr. Moskowitz; Panchal, Sunil; Dr. Passik; Russell Portenoy, MD; Dr. Sinatra; Lars Arendt-Nielsen  
**Cc:** Silva, Laura; Kaiko, Dr Robert  
**Subject:** Portfolio Advisory Meeting - May 18, 2011  
**Attachments:** PAB May2011 Draft Agenda.docx

All,  
The APS Conference is May 19 – 21, 2011 and the PAB meeting will be held 1-day prior on May 18, 2011.

Here is the link to the APS website:  
<http://www.ampainsoc.org/>

I will need to understand if you are only attending PAB in order to secure rooms at the Hilton Austin.

If you are attending APS & PAB your hotel will be directly booked with the APS conference registration.

Any questions, please contact me directly.

Thank you.

*Nancy Camp-Font*  
Assistant to Craig Landau, MD  
Vice President & Chief Medical Officer  
and  
Assistant to Bob Kaiko, PhD  
Vice President R&D Portfolio Development  
Purdue Pharma  
One Stamford Forum  
Stamford, CT 06901  
203-588-7240  
203-588-6106  
[nancy.camp-font@pharma.com](mailto:nancy.camp-font@pharma.com)

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**AGENDA**

**Portfolio Advisory Board (PAB)**  
**Face-to-Face Meeting**  
**May 18, 2011**  
**Hilton, Austin TX**  
**12PM – 6PM**

<b>TIME</b>	<b>TOPIC</b>	<b>PRESENTER</b>
	<b>Working Lunch (12:00)</b>	
12:00 – 12:15PM	<b>Welcome &amp; Introductions</b>	<b>Bob Kaiko Ray Sinatra</b>
12:15 – 12:45PM	<b>Discovery / Early Development Novel Targets</b>	<b>D. Kyle</b>
12:45 – 1:15PM	<b>Evaluation of Potential Dosage Forms</b>	<b>D. Rosen?</b>
1:15 – 2:30PM	<b>Unmet Needs &amp; Opportunities in Pain Management: Now and in the Future</b>	<b>J. Gudin R. Sinatra</b>
2:30 – 3:15PM	<b>Unmet needs &amp; Opportunities in GI Now and in the Future</b>	<b>A. Gorelick R. Sinatra</b>
3:15 – 3:30PM	<b>Break</b>	
3:30 – 4:00PM	<b>Early Clinical Compounds</b>	<b>X. Ning</b>
4:00 – 4:30PM	<b>ONU Update</b>	<b>J. Green</b>
4:30 – 5:00PM	<b>Abuse Liability Study Endpoints</b>	<b>S. Harris</b>
5:00 – 5:50PM	<b>Risk Management as a Means to Support Clinical Practice, Pain Management &amp; Patient Access</b>	<b>P. Coplan</b>
5:50 – 6:00PM	<b>Closing</b>	<b>Ray Sinatra Bob Kaiko</b>
7:00PM	<b>Dinner Location TBD</b>	<b>All</b>

**Russell Portenoy, MD**

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**From:** Russell Portenoy, MD  
**Sent:** Friday, April 15, 2011 10:28 AM  
**To:** 'Camp-Font, Nancy'  
**Cc:** Donna Reid  
**Subject:** RE: PAB/Purdue Meeting - May 18, 2011

Dear Ms. Camp-Font,

I am afraid that another commitment has appeared and I will be unable to travel to the meeting. I am sorry about this.

Would Drs. Kaiko, Landau and Sinatra want to participate by teleconference, at least for part of the meeting?

Russ Portenoy MD

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**From:** Camp-Font, Nancy [mailto:Nancy.Camp-Font@pharma.com]  
**Sent:** Friday, April 01, 2011 1:53 PM  
**To:** Adam Gorelick; Dr. Candiotti; Dr. Fine; Gudin, Jeffery; Katz, Nathaniel; Dr. Kehlet; Kelley, John; Dr. Kryger; Dr. McCarberg; Miaskowski, Christine; Dr. Moskowitz; Panchal, Sunil; Dr. Passik; Russell Portenoy, MD; Dr. Sinatra; Lars Arendt-Nielsen  
**Cc:** Kaiko, Dr Robert; Silva, Laura; Landau, Dr. Craig  
**Subject:** PAB/Purdue Meeting - May 18, 2011

Dear Members,

Please let me know if you have a preference with the meeting starting at 9:00AM on Wednesday, May18th vs. the currently scheduled start time of 12:00PM.

Thank you.

Nancy Camp-Font  
Assistant to Craig Landau, MD  
Vice President & Chief Medical Officer  
and  
Assistant to Bob Kaiko, PhD  
Vice President R&D Portfolio Development  
Purdue Pharma  
One Stamford Forum  
Stamford, CT 06901  
203-588-7240  
203-588-6106  
[nancy.camp-font@pharma.com](mailto:nancy.camp-font@pharma.com)

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**Russell Portenoy, MD**

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**From:** Russell Portenoy, MD  
**Sent:** Friday, April 22, 2011 2:46 PM  
**To:** 'Kaiko, Dr Robert'  
**Cc:** Donna Reid  
**Subject:** RE:

Bob,

Thanks very much. We'll put the idea of a study of Butrans in opioid-naïve breast cancer survivors with chronic treatment-related pain on hold till you get back to me.

Florida vs. Austin—quite a decision. But sadly, no, I can't make either. I will be in NYC for most of the week and would of course be delighted to meet before or after. Let me know if you want to do this and what timing would you suggest.

Russ

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**From:** Kaiko, Dr Robert [mailto:Dr.Robert.Kaiko@pharma.com]  
**Sent:** Friday, April 22, 2011 12:47 PM  
**To:** Russell Portenoy, MD  
**Subject:** RE:

Russ

Thanks for your note. If it makes a difference our meeting is in Austin on May 18<sup>th</sup>, not in Florida. I'd really like to get your input face-to-face. Rather than teleconferencing you into the meeting, would you consider meeting with a couple of us at your convenience just before or after May 18<sup>th</sup>?

We are currently contemplating the support of investigator-initiated trials for Butrans and other products but at this time we have no such programs. I'd like to get back to you in respect to the outcomes of our ongoing deliberations shortly. Meanwhile, we appreciate the opportunity to support such work.

Warmest,  
bk

Robert F. Kaiko, Ph.D.  
Vice President R&D Portfolio Development  
Purdue Pharma  
One Stamford Forum  
Stamford, CT 06901-3431  
203-588-7210  
203-588-6106 (fax)  
[dr.robert.kaiko@pharma.com](mailto:dr.robert.kaiko@pharma.com)

IMPORTANT NOTICE: This message is intended only for the use of the individual or entity to which it is addressed. The message may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient, or the employee or agent responsible for delivering the message to the intended recipient, you are notified that any dissemination, distribution or copying of this communication is strictly prohibited.

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**From:** Russell Portenoy, MD [mailto:RPorteno@chpnet.org]  
**Sent:** Tuesday, April 19, 2011 7:18 AM  
**To:** Kaiko, Dr Robert  
**Subject:**

Dear Bob,

I hope all is well. I wanted to let you know that I cannot make it to Florida for the next meeting of the advisory board because of another commitment, but I would be able to clear some hours to be on the phone. I realize that this may have limited value and it would be OK (and understandable) if you or Ray opted not to take me up on this. I would understand either way.

I also have a quick question for you: A young oncologist is interested in doing a small trial of Butrans in a pain syndrome related to a specific treatment in breast cancer survivors. I told her that it was a great idea and would find out whether Purdue has a program to support investigator-initiated trials with this drug. Does such a program exist, and if so, how does one get more info about it.

I am sorry that I will not see you in May. Thanks much.

Russ  
This message and any attachments are confidential and intended solely for the use of the individual or entity to which they are addressed. If you are not the intended recipient, you are prohibited from printing, copying, forwarding, saving, or otherwise using or relying upon them in any manner. Please notify the sender immediately if you have received this message by mistake and delete it from your system.



**Russell Portenoy, MD**

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**From:** Camp-Font, Nancy [Nancy.Camp-Font@pharma.com]  
**Sent:** Friday, May 13, 2011 11:45 AM  
**To:** Adam Gorelick; Dr. Candiotti; Dr. Fine; Gudin, Jeffery; Katz, Nathaniel; Dr. Kehlet; Kelley, John; Dr. Kryger; Dr. McCarberg; Miaskowski, Christine; Dr. Moskowitz; Panchal, Sunil; Dr. Passik; Russell Portenoy, MD; Dr. Sinatra; Lars Arendt-Nielsen  
**Cc:** Kaiko, Dr Robert; Silva, Laura; Landau, Dr. Craig  
**Subject:** PAB Meeting Final Agenda - PreMeeting Questions  
**Attachments:** PAB May2011Final Agenda.docx; PAB Premeeting Questions.docx

All,

Please find attached an agenda and pre-meeting questions for our PAB meeting in Austin on Wednesday, May 18<sup>th</sup>.

Feel free to contact me with any last minute questions.

Thank you.

*Nancy Camp-Font*  
Assistant to Craig Landau, MD  
Vice President & Chief Medical Officer  
and  
Assistant to Bob Kaiko, PhD  
Vice President R&D Portfolio Development  
Purdue Pharma  
One Stamford Forum  
Stamford, CT 06901  
203-588-7240  
203-588-6106  
[nancy.camp-font@pharma.com](mailto:nancy.camp-font@pharma.com)

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**AGENDA****Portfolio Advisory Board (PAB)****Face-to-Face Meeting****May 18, 2011****Hilton, Austin TX****12PM – 6PM**

<b>TIME</b>	<b>TOPIC</b>	<b>PRESENTER</b>
	<b>Working Lunch (12:00) - Salon A Meeting Location = Room 614</b>	
12:00 – 12:15PM	<b>Welcome &amp; Introductions</b>	<b>Bob Kaiko Ray Sinatra</b>
12:15 – 12:45PM	<b>Discovery / Early Development Novel Targets</b>	<b>D. Kyle</b>
12:45 – 1:15PM	<b>Evaluation of Potential Dosage Forms</b>	<b>G. Bock</b>
1:15 – 2:30PM	<b>Unmet Needs &amp; Opportunities in Pain Management: Now and in the Future</b>	<b>J. Gudin R. Sinatra</b>
2:30 – 3:15PM	<b>Unmet needs &amp; Opportunities in OIC / OBD Now and in the Future</b>	<b>A. Gorelick R. Sinatra</b>
3:15 – 3:30PM	<b>Break</b>	
3:30 – 4:00PM	<b>Early Clinical Compounds – Phase 2 Planning</b>	<b>X. Ning</b>
4:00 – 4:30PM	<b>ONU Update</b>	<b>J. Green</b>
4:30 – 5:00PM	<b>Abuse Liability Study Endpoints</b>	<b>S. Harris</b>
5:00 – 5:50PM	<b>Risk Management as a Means to Support Clinical Practice, Pain Management &amp; Patient Access</b>	<b>P. Coplan</b>
5:50 – 6:00PM	<b>Closing</b>	<b>Ray Sinatra Bob Kaiko</b>
7:00PM	<b>Dinner Parkside Restaurant 301 East 6<sup>th</sup> Street Austin, TX 78701 512-474-9898</b>	<b>All</b>

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**1. Discovery / Early Development Novel Targets**

- a. PAB thoughts regarding the concept of a new epidural opiate (that provides comparable or better analgesic efficacy than morphine, but without the itch side effect?)
- b. PAB thoughts regarding the concept of a new pathway selective opiate & route(s) of administration (oral versus transdermal)?
- c. PAB thoughts regarding the concept of weak delta opiate antagonist in combination with a classical mu agonist for reduction/elimination of side effects?

**2. Evaluation of Potential Dosage Forms**

- a. Please consider some of the common dosage forms available in prescription medications today:
  - i. Patch
  - ii. Gel
  - iii. Ointment
  - iv. Tablet – different shapes
  - v. Capsule
  - vi. Buccal
  - vii. Intranasal
  - viii. Oral dissolving tablet
  - ix. Thin strip
  - x. Others
- b. What are some of the positives and negatives of these dosage forms based on your experiences?
- c. In your clinical practice, what do you see as the main unmet needs with respect to dosage form? In other words, can you think of particular medications (pain, insomnia, or otherwise) where clinical practice may be improved by having an alternative dosage form? What medications and what dosage forms?

**3. Unmet needs & Opportunities in OIC / OBD: Now and in the Future**

- a. Scope of the problem/how important?
- b. Unmet needs- for the MD, for the patient
- c. QOL issues
- d. Indications for treatment- prevention vs rescue therapy
- e. Naloxone products-single vs combination products

*Dedicated to Physician and Patient*

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- f. Peripheral  $\mu$ -opioid receptor antagonists
- g. Can we do better?
- h. What can we learn from other treatments for constipation (CIC, IBS-C)?
- i. Opportunities for combination therapy with traditional agents?
- j. Other opportunities

#### **4. Early Clinical Compounds – Phase 2 Planning**

- a. TRPV1 antagonists are being intensively researched, developed and published. From what you have observed, what are the challenges and opportunities for this class of compound?
- b. V116517/ TRPV1 antagonists has broad animal efficacy and broad potential indications. Please help us prioritize these indications for initial Ph II studies.
- c. Neuropathic pain is a potential indication for V116517/ TRPV1 antagonists. However, there are many types of neuropathic pain. Which ones should we start with?
- d. Please help us with choice of active comparators considering the mechanism, standard of care and market competitiveness.

#### **5. Abuse Liability Study Endpoints**

- a. What tampering and/or abuse liability studies should be considered for ONU?
- b. How useful would a reformulation of ONU that is physico-chemically tamper-resistant be?
- c. What abuse potential study setting and endpoints are most relevant to abuse liability assessment?
- d. What are primary considerations regarding risk/benefit for public dissemination of abuse potential study results?
- e. Is there utility in head-to-head abuse potential comparisons among putative ‘abuse-resistant’ controlled-release opioid formulations?
- f. How do Prescribers / Payors / Regulators view the relative merits of:
  - i. Pharmacological deterrents with no other value?
    - 1. Sequestered
    - 2. Non-sequestered
  - ii. Pharmacological deterrents with intrinsic clinical utility?
  - iii. Physico-chemical tamper deterrents?
- g. How important is development of intact high-dose/overdose protection (eg low-dose subclinical pharmacologic deterrent)?

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- h. What data should be required to support labeling statements regarding:
  - i. Tamper resistance?
  - ii. Abuse deterrence?
- i. How does the introduction of tamper-resistant and/or abuse deterrent long-acting opioids affect the acceptability of formulations without these properties?

**Russell Portenoy, MD**

---

**From:** Camp-Font, Nancy [Nancy.Camp-Font@pharma.com]  
**Sent:** Friday, May 20, 2011 8:52 AM  
**To:** Camp-Font, Nancy; Adam Gorelick; Dr. Candiotti; Dr. Fine; Gudín, Jeffery; Katz, Nathaniel; Dr. Kehlet; Kelley, John; Dr. Kryger; Dr. McCarberg; Miaskowski, Christine; Dr. Moskowitz; Panchal, Sunil; Dr. Passik; Russell Portenoy, MD; Dr. Sinatra; Lars Arendt-Nielsen  
**Subject:** RE: PAB Consultant Invoice Template  
**Attachments:** PAB consultant invoice template 2011.xlsx

Sorry forgot the attachment!

Nancy Camp-Font  
Assistant to Craig Landau, MD  
Vice President & Chief Medical Officer  
and  
Assistant to Bob Kaiko, PhD  
Vice President R&D Portfolio Development  
Purdue Pharma  
One Stamford Forum  
Stamford, CT 06901  
203-588-7240  
203-588-6106  
[nancy.camp-font@pharma.com](mailto:nancy.camp-font@pharma.com)

---

**From:** Camp-Font, Nancy  
**Sent:** Friday, May 20, 2011 8:45 AM  
**To:** 'Adam Gorelick'; 'Dr. Candiotti'; 'Dr. Fine'; 'Dr. Gudín'; 'Dr. Katz'; 'Dr. Kehlet'; 'Dr. Kelley'; 'Dr. Kryger'; 'Dr. McCarberg'; 'Dr. Miaskowski'; 'Dr. Moskowitz'; 'Dr. Panchal'; 'Dr. Passik'; 'Dr. Portenoy'; 'Dr. Sinatra'; 'Lars Arendt-Nielsen'  
**Subject:** PAB Consultant Invoice Template

All,  
Thank you for joining us in Austin on Wednesday for the 3<sup>rd</sup> Annual PAB Meeting. Please forward any comments or suggestions on improving our next meeting.

I have attached the consultant invoice template for your use in submitting your expenses. I will need the original receipts mailed to my attention at the address below.

Thanks again and see you soon!

Nancy Camp-Font  
Assistant to Craig Landau, MD  
Vice President & Chief Medical Officer  
and  
Assistant to Bob Kaiko, PhD  
Vice President R&D Portfolio Development  
Purdue Pharma  
One Stamford Forum  
Stamford, CT 06901  
203-588-7240  
203-588-6106  
[nancy.camp-font@pharma.com](mailto:nancy.camp-font@pharma.com)





P.O. \_\_\_\_\_

[illegible]

**Russell Portenoy, MD**

---

**From:** Donna Reid  
**Sent:** Friday, May 20, 2011 2:45 PM  
**To:** Russell Portenoy, MD  
**Subject:** FW: Portfolio Advisory Board Discussion

Donna Reid  
Administrative Assistant II  
Beth Israel Medical Center  
Department of Pain Medicine and Palliative Care  
First Ave at 16th St  
New York, NY 10003  
Phone: 212-844-1505  
Fax: 212-844-1503

---

**From:** Russell Portenoy, MD  
**Sent:** Monday, May 16, 2011 4:21 PM  
**To:** 'Camp-Font, Nancy'  
**Cc:** Donna Reid  
**Subject:** RE: Portfolio Advisory Board Discussion

Let me ask Donna Reid in my office to respond. Thanks.

---

**From:** Camp-Font, Nancy [mailto:Nancy.Camp-Font@pharma.com]  
**Sent:** Monday, May 16, 2011 3:24 PM  
**To:** Russell Portenoy, MD  
**Subject:** Portfolio Advisory Board Discussion

Dr. Portenoy,  
Dr. Kaiko was hoping to speak with you sometime the first week in June. Are you available in NYC or to come to Stamford on June 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup>?

Nancy Camp-Font  
Assistant to Craig Landau, MD  
Vice President & Chief Medical Officer  
and  
Assistant to Bob Kaiko, PhD  
Vice President R&D Portfolio Development  
Purdue Pharma  
One Stamford Forum  
Stamford, CT 06901  
203-588-7240  
203-588-6106  
[nancy.camp-font@pharma.com](mailto:nancy.camp-font@pharma.com)

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**Russell Portenoy, MD**

---

**From:** Kaiko, Dr Robert [Dr.Robert.Kaiko@pharma.com]  
**Sent:** Wednesday, June 01, 2011 4:03 PM  
**To:** Russell Portenoy, MD  
**Cc:** Donna Reid  
**Subject:** RE: 2pm telecon tomorrow

Russ

Hope all is well with you and yours.

In preparation for tomorrow's 2pm telecom let me point out that we will be focusing on (see agenda in document you were recently mailed):

- a. Early clinical compounds – Phase II planning
- b. ONU update
- c. Abuse liability endpoints

We may need to set up another session (or 2) at a later date.

Regards,  
bk

Robert F. Kaiko, Ph.D.  
Vice President R&D Portfolio Development  
Purdue Pharma  
One Stamford Forum  
Stamford, CT 06901-3431  
203-588-7210  
203-588-6106 (fax)  
[dr.robert.kaiko@pharma.com](mailto:dr.robert.kaiko@pharma.com)

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**From:** Russell Portenoy, MD [mailto:RPorteno@chpnet.org]  
**Sent:** Friday, April 22, 2011 2:46 PM  
**To:** Kaiko, Dr Robert  
**Cc:** Donna Reid  
**Subject:** RE:

Bob,

Thanks very much. We'll put the idea of a study of Butrans in opioid-naïve breast cancer survivors with chronic treatment-related pain on hold till you get back to me.

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**Russell Portenoy, MD**

---

**From:** Camp-Font, Nancy [Nancy.Camp-Font@pharma.com]  
**Sent:** Thursday, June 09, 2011 8:27 AM  
**To:** Russell Portenoy, MD  
**Cc:** Donna Reid  
**Subject:** RE: Opioid Risk Management, OxyContin

Donna,

Please let me know if Dr. Portenoy is available for 1 hr on July 6<sup>th</sup> at 10:30AM. Thank you.

If not, please propose some July dates for a 1 HR discussion on the above topic. Thanks.

*Nancy Camp-Font*

Assistant to Craig Landau, MD  
Vice President & Chief Medical Officer  
and  
Assistant to Bob Kaiko, PhD  
Vice President R&D Portfolio Development  
Purdue Pharma  
One Stamford Forum  
Stamford, CT 06901  
203-588-7240  
203-588-6106  
[nancy.camp-font@pharma.com](mailto:nancy.camp-font@pharma.com)

---

**From:** Russell Portenoy, MD [mailto:RPorteno@chpnet.org]  
**Sent:** Wednesday, June 08, 2011 4:17 PM  
**To:** Kaiko, Dr Robert  
**Cc:** Coplan, Paul; Camp-Font, Nancy; Silva, Laura; Donna Reid  
**Subject:** RE: Opioid Risk Management, OxyContin

Bob,  
Of course.  
Russ

---

**From:** Kaiko, Dr Robert [mailto:Dr.Robert.Kaiko@pharma.com]  
**Sent:** Wednesday, June 08, 2011 4:01 PM  
**To:** Russell Portenoy, MD  
**Cc:** Coplan, Paul; Camp-Font, Nancy; Silva, Laura  
**Subject:** Opioid Risk Management, OxyContin

Russ

Thanks again for the recent telecon. It was most helpful.

As I'd mentioned we'd like to do another one or so and, if you are willing. I'd like to schedule one for you and Paul Coplan to discuss opioid risk management issues, including what we're doing with OxyContin. I'll ask Nancy to schedule an hour for the three of us. I don't think this can happen until July. Okay?

Thanks,  
bk

Robert F. Kaiko, Ph.D.  
Vice President R&D Portfolio Development  
Purdue Pharma  
One Stamford Forum  
Stamford, CT 06901-3431  
203-588-7210  
203-588-6106 (fax)  
[dr.robert.kaiko@pharma.com](mailto:dr.robert.kaiko@pharma.com)

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tel +1 212 / 460 15 00  
fax +1 212 / 620 84 42  
www.springerhealthcare.com

January 25, 2011

Dr. Russell Portenoy  
Department of Pain Medicine  
Beth Israel Medical Center  
First Avenue and 16th Street  
New York, NY 10003

*Donna,  
Keep copy + overnight mail  
return by Thanks*

Dear Dr. Portenoy,

Enclosed please find printout of all of the content for the Purdue Opioid Resource CD-ROM.  
The pages are in the order they will appear, and the scripts have been inserted into the proper locations.

Please let me know if you have any questions. Thank you.

Sincerely,



Stephanie Leveene  
Medical Writer  
Springer Healthcare LLC  
Phone: 212-460-1555  
Fax : 212-620-8442  
E-mail : stephanie.leveene@springer.com



Welcome to PERFORM: Patient Evaluation Resources for Opioid Risk Management. This resource is designed to provide you with information on how to assess risk of medication abuse in your patients who are on short- or long-term opioid therapy. Here, you will find interactive case vignettes, illustrating low-, medium-, and high-risk patients, pain assessment and risk assessment tools, documentation and monitoring information, and other valuable educational materials.

Move your mouse around the doctor's office to access the different sections, or click the bars on the left-hand side.

[Purdue logo]

[SH logo]

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### General Safety Information on Opioids

As with all medications, indications and usage for specific opioid analgesics vary and the Full Prescribing Information (FPI) for each specific product being referenced should be consulted. Proper patient selection and assessment, proper prescribing practices, periodic re-evaluation of therapy, proper dispensing, and correct storage, handling and disposal are appropriate measures that help to limit the diversion and abuse of opioid drugs. Careful record-keeping of prescribing information, including quantity, frequency, and renewal requests is strongly advised.

**Counsel**  
**Overdose**  
Instruct patients ~~never to share their medications with others and to make sure that they are secured in a safe place.~~ *never to share their medications with others and to make sure that they are secured in a safe place.*  
~~against the use by individuals other than the patient for whom you have prescribed the opioid analgesic, as such inappropriate use may have severe medical consequences, including death. Persons who are not prescribed an opioid analgesic can overdose by taking even one dose. Persons who have a prescription for an opioid analgesic can overdose by taking more than the amount prescribed.~~ *opioid-naïve*  
*are taking an opioid chronically*

*An*  
Certain doses of specific opioid analgesics may cause fatal respiratory depression if taken by patients who have not developed tolerance to the respiratory depressant or sedating effects of opioids.

*(a formulation (eg chewing a modified-release tablet))*  
Manipulation by any means of any opioid analgesic dosage form poses a significant risk that could result in overdose and death. The risk of fatal outcome is increased with concurrent use or abuse of alcohol or other CNS depressants.

### **Respiratory Depression**

Respiratory depression is the most significant serious adverse event risk with all opioid agonists, *And* ~~which~~ can result in death.

*and in patients receiving*  
The risk of respiratory depression is increased in elderly or debilitated patients, usually following large initial doses ~~in persons who have not developed any degree of tolerance to the respiratory depressant or sedating effects of opioid analgesics, or when opioids are given in conjunction with other agents that depress respiratory drive or consciousness.~~

### **Addition, Abuse, and Diversion**

~~There is a potential for drug addiction to develop following exposure to opioids even under appropriate medical use.~~ All patients treated with opioids require careful monitoring for signs of abuse and addiction.

Opioid agonists have the potential to be abused and are subject to criminal diversion. Educate patients that sharing, giving, loaning, and selling one's opioid analgesics are dangerous and unlawful.

*Always address non-adherence, a frank abuse. Reassess, determine the cause, make a tentative diagnosis of addiction if appropriate, and decide whether to stop the drug, continue, or refer to addiction evaluation.*

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### Physical Dependence and Tolerance

The development of physical dependence and/or tolerance is ~~not unusual~~ *should be assumed to occur* during chronic opioid therapy.

When a patient no longer requires therapy with an opioid, the daily dose should be tapered gradually to prevent signs and symptoms of withdrawal syndrome in the physically-dependent patient.

### Contraindications

Opioids are contraindicated in any setting with a risk of significant respiratory depression, in patients who have acute or severe bronchial asthma, in patients who have or are suspected of having paralytic ileus, or in patients with known hypersensitivity to any of the opioid product's constituents. *must be used very cautiously otherwise predisposed to opioid side effects.*

### Serious Side Effects

Respiratory depression, apnea, respiratory arrest, and to a lesser degree, circulatory depression, hypotension, shock, or cardiac arrest have all been associated with opioid use and abuse.

### Common Side Effects

Nausea, vomiting, dizziness, ~~drowsiness~~, constipation, ~~itching~~, dry mouth, sweating, weakness, and headache are the most common non-serious side effects of opioid analgesics. *mental clouding, drowsiness*

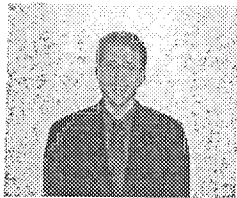
Opioid analgesics may cause ~~drowsiness, dizziness, or lightheadedness~~ and may impair mental and/or physical ability required for the performance of potentially hazardous tasks (e.g. driving, operating machinery). Patients should be cautioned accordingly.

### Storage, Handling and Disposal

Patients should be counseled about the importance of storing opioid analgesics safely and out of reach of children, other household members, visitors and pets, and protected from theft or misuse. Accidental consumption especially in children may result in overdose or death. When opioid analgesics are no longer needed, they should be disposed of in the manner described in the FPI or on the FDA website at:

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm#MEDICINES>

## Advisory Panel



Charles E. Argoff, MD, is Professor of Neurology at Albany Medical College and Director of the Comprehensive Pain Program at Albany Medical Center in Albany, New York. He is Chair of the Fundamentals of Pain Management Course Steering Committee and a member of the Education Committee of the American Pain Society. He is also Chair of the Pain Management Task Force of the Medical Education and Scientific Foundation, Medical Society of the State of New York.

Dr. Argoff's areas of interest include the use of Botox for the treatment of chronic low back pain and myofascial pain associated with reflex sympathetic dystrophy, potential mechanisms for fibromyalgia in peripheral tissue innervation, and the use of topical lidocaine to reduce pain in patients with diabetic neuropathy. He is the author or co-author of numerous book chapters, and is co-editor of the books *Pain Management Secrets, 3rd Edition* and *Raj's Practical Management of Pain, 4th Edition*. Dr. Argoff is the Neuropathic Pain Section co-editor of *Pain Medicine* and the Pain Section Contributing Editor of *Practical Neurology*. He also sits on the editorial boards of *Applied Neurology*, *BMC Neurology*, and the *Clinical Journal of Pain*.



Paul J. Christo, MD, MBA, is Director of the Multidisciplinary Pain Fellowship Program at The Johns Hopkins Hospital in Baltimore, Maryland. Dr. Christo has board certifications in pain medicine from the American Academy of Pain Medicine and American Board of Anesthesiology.

Dr. Christo serves on the Pain.com Advisory Board for the Dannemiller Memorial Educational Foundation and has served on the Committee on Pain Medicine of the American Society of Anesthesiologists. He received a Media Fellowship by the Mayday Pain and Society Fellowship Program: A Media and Policy Initiative in 2008-2009. He was one of six pain experts selected from the United States and Canada to advocate for better pain treatment by raising visibility with the media and policymakers.

Dr. Christo has published on such topics as the use of botulinum toxin for thoracic outlet syndrome, procedural elements of pain medicine, postherpetic neuralgia (shingles-related pain), opioid effectiveness in chronic pain, aging and addiction, cancer pain, and complex regional pain syndrome. He is currently investigating novel therapies for the treatment of chronic pain syndromes such as thoracic outlet syndrome, and studying the sexual side effects of chronic opioid therapy, pain medication prescription errors, and online educational modules for pain education. Dr. Christo's areas of expertise include spine pain (low back and neck pain), cancer pain, disc herniations and degenerative disc disease, neuropathic pain (reflex sympathetic dystrophy or complex regional pain syndrome), shingles pain (postherpetic neuralgia), thoracic outlet syndrome, implantations (spinal cord stimulators/intrathecal pumps) for persistent pain, clinical anesthesia, epidural placement, and spinal anesthesia.



**Steven D. Passik, PhD**, is Associate Professor of Psychology at Weill Cornell Medical College in New York City. He is also Associate Attending Psychology at Memorial Sloan-Kettering Cancer Center and Clinical Psychologist at the Rockefeller University Hospital, both in New York City.

Dr. Passik is a founding member of the International Association of Pain and Chemical Dependency and sits on its Board of Directors. He is a member of several other medical societies, including the American Pain Society, the Academy of Psychosomatic Medicine, and the International Association for the Study of Pain.

Dr. Passik has authored or co-authored over 200 journal articles, book chapters, and abstracts on opioid therapy, palliative care, and other topics in cancer- and noncancer-related pain management. He is co-editor of the books *Opioid Risk Management—Tools and Tips*, *Pain and Chemical Dependency*, and *The Expert Guide to Pain Management*. Dr. Passik sits on the editorial boards of the *Journal of Pain and Symptom Management* and the *Journal of Pain & Palliative Care Pharmacotherapy*. He has presented at numerous local, national, and international conferences.



Russell K. Portenoy, MD, is chairman of the Department of Pain Medicine and Palliative Care and the Gerald J. Friedman Chair in Pain Medicine and Palliative Care at Beth Israel Medical Center New York in New York City. He is also Professor of Neurology and Anesthesiology at Albert Einstein College of Medicine of Yeshiva University in Bronx, New York, and also serves as the Chief Medical Officer of MJHS Hospice and Palliative Care.

Dr. Portenoy is past president of the American Pain Society and the American Academy of Hospice and Palliative Medicine. He is the recipient of the National Leadership Award of the American Academy of Hospice and Palliative Medicine, the Wilbert Fordyce Award for Lifetime Excellence in Clinical Investigation and the Distinguished Service Award from the American Pain Society, and the Founder's Award from the American Academy of Pain Medicine. He currently serves on the Board of Directors of the American Pain Foundation.

Dr. Portenoy is editor in chief of the *Journal of Pain and Symptom Management* and editor of the palliative care section of *The Oncologist*. He serves on numerous other editorial boards and has written, co-authored, or edited 20 books and more than 500 papers and book chapters on topics in pain and symptom management, opioid pharmacotherapy, and symptom assessment.

## Recommendations for the Use of Opioids

The American Pain Society, in its 2009 Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain, have these recommendations for patient selection and risk stratification:

“Before initiating COT [chronic opioid therapy], clinicians should conduct a history, physical examination and appropriate testing, including risk assessment for substance abuse, misuse, or addiction. Clinicians may consider a trial of COT as an option if chronic, noncancer pain is moderate or severe, pain is having an adverse impact on function or quality of life, and potential therapeutic benefits outweigh or are likely to outweigh potential harms.”<sup>1</sup>

The American Geriatrics Society has issued similar guidelines for prescribing and managing opioid therapy when treating persistent pain in the elderly:

“All patients with moderate to severe pain, pain-related functional impairment, or diminished quality of life due to pain should be considered for opioid therapy. Patients taking opioid analgesics should be reassessed for ongoing attainment of therapeutic goals, adverse effects, and safe and responsible medication use.”<sup>2</sup>

### References

1. Chou R, Fanciullo GJ, Fine PG, et al, for the American Pain Society–American Academy of Pain Medicine Opioids Guidelines Panel. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain*. 2009;10:113-130.
2. American Geriatrics Society Panel on the Pharmacological Management of Persistent Pain in Older Persons. Pharmacological management of persistent pain in older persons. *J Am Geriatr Soc*. 2009;57:1331-1346.

## Patient Evaluation Tools

This section provides links to risk assessment and patient inventory tools for the health care practitioner to use during both initial evaluations and follow-up visits. The results gathered from these instruments assist in the determining what the appropriate course of therapy should be (choice of agent, length of treatment regimen, etc.), as well as what and how much patient monitoring should be done.

There are many patient evaluation tools available; these represent a sample. In your practice, you can use these or other tools alone, or combine them with clinical risk stratification through interviews and evaluations of the patient's psychiatric history.

[clickable button for Risk Assessment Tools page]

[clickable button for Pain Inventory Tools page]

Patient Evaluation Tools: Risk Assessment  
CAGE-AID

[video]

[link to downloadable CAGE-AID PDF]



## Script

### Patient Evaluation Tools: Risk Assessment

#### CAGE-AID

Cell	Visual	Audio
101	KTL onscreen.	<b>Narrator:</b> The original CAGE questionnaire was developed by Richard Brown and colleagues to screen patients who may be at risk for alcohol abuse. The CAGE-Adapted to Include Drugs, or CAGE-AID, added language that includes drug use.
102	Close-up on the 4 questions of the CAGE-AID tool (don't show the bullets at the bottom). Add animation of checks as follows (in order):  1. Yes 2. No 3. No 4. Yes	<b>Narrator:</b> It is primarily used at initial evaluations and should be followed up with a more detailed questionnaire if patients respond positively to 2 or more of the questions.
103	KTL onscreen.	<b>Narrator:</b> CAGE-AID is short and very easy to administer. However, it has not been validated for specific use in patients with pain. It also may have less predictive value in college students, women, the elderly, and some ethnic groups.

**Patient Evaluation Tools: Risk Assessment Tools**  
**Opioid Risk Tool (ORT)**

[video]

Patient Version

[link to downloadable Opioid Resource tool PDF—Patient Version]

Physician Version

[link to downloadable Opioid Resource tool PDF—Physician Version]

**Script****Patient Evaluation Tools: Risk Assessment  
Opioid Resource Tool (ORT)**

Cell	Visual	Audio
101	KTL onscreen.	<b>Narrator:</b> The Opioid Resource Tool, or ORT, is aimed at measuring and calculating a patient's probability for substance abuse or aberrant behaviors while taking opioids. It was developed by Lynn Webster and colleagues specifically for use in patients on opioid therapy for chronic pain, and stratifies patients into low-, medium-, and high-risk categories.
102	Close-up of ORT form (physician version). Add animation of check marks to the following, in this order:  2. Check "Alcohol" 5. Check "Depression" 3. Check box	<b>Narrator:</b> Patients are asked questions about personal and family histories of alcohol or drug abuse (either illegal and prescription drugs), a history of preadolescent sexual abuse, and psychological disease. Different points are assigned to each answer, depending on whether the patient is male or female. An extra point is given if the patient is between 16 and 45 years old.
103	Onscreen text:  Risk Categories  <ul style="list-style-type: none"> <li>• 0-3 points: low risk</li> <li>• 4-7 points: moderate risk</li> <li>• ≥8 points: high risk</li> </ul>	<b>Narrator:</b> Risk categories are as follows:  <ul style="list-style-type: none"> <li>• 0-3 points is considered low risk</li> <li>• 4-7 points is considered moderate risk</li> <li>• 8 or more points is considered high risk</li> </ul>
104	KTL onscreen.	<b>Narrator:</b> The ORT is easy to use and takes less than 5 minutes to administer. However, <del>patients can decide to withhold information, thus skew the overall score.</del> Therefore, <del>it is important +</del> health care providers should use the

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*it has not been adequately validated.*

		ORT in combination with <del>other tools</del> and <del>watch for any patterns in</del> <del>aberrant behavior.</del>
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← a careful clinical  
assessment.

## Patient Evaluation Tools

### ~~Pain Inventory Tools~~

~~Pain inventory tools help determine the patient's level and intensity of pain. Depending on the degree of pain, either a short- or long-term course of opioid therapy may be prescribed, with dosage levels based on the information obtained. Knowing how the intensity of the patient's pain is especially important in determining if he or she need to be on long-term therapy. However, assessment is not the same as inventory, and pain should be characterized based on such factors as etiology and prior treatments.~~

[link to Brief Pain Inventory page]

[link to PADT page]

[link to Simple Descriptive Pain Intensity Scale page]

measure and track

and decision of pain-related outcomes,  
The decision to initiate a trial of  
opioid therapy for chronic pain,  
and the essential  
process of  
monitoring therap;  
over time is

Facilitate  
by the  
use of  
tools that  
provide, informs  
that can be be  
used to risk stratify  
and judge long-term  
benefits and burden.

*and pain interference with functional domains.*

## Patient Evaluation Tools: Pain Inventory

### Brief Pain Inventory

The Brief Pain Inventory (BPI) was developed by Charles Cleeland and colleagues to provide an easy way of measuring pain intensity. It ~~also~~ rates how pain affects aspects of daily living, including sleep, mood, relationships, and work. The BPI is available in both short- and long-form versions; the short form is included here.

A user's guide to the BPI can be found at the M.D. Anderson Cancer Center Website:  
[http://www.mdanderson.org/education-and-research/departments-programs-and-labs/departments-and-divisions/symptom-research/symptom-assessment-tools/BPI\\_UserGuide.pdf](http://www.mdanderson.org/education-and-research/departments-programs-and-labs/departments-and-divisions/symptom-research/symptom-assessment-tools/BPI_UserGuide.pdf)

[video]

[link to downloadable Brief Pain Inventory PDF]

## Script

Patient Evaluation Tools/ ~~Pain Inventory~~

## Brief Pain Inventory

Cell	Visual	Audio
101	KTL onscreen.	<b>Narrator:</b> The Brief Pain Inventory (BPI) was developed by Charles Cleeland and colleagues to provide an easy way of measuring pain intensity. It also rates how pain affects aspects of daily living, including sleep, mood, relationships, and work.
102	<p>Show these words on the screen:</p> <p>The Brief Pain Inventory was first used in patients with cancer and has since been validated in those with chronic nonmalignant pain.</p> <p>[Make sure this text is at the bottom of the screen, in smaller type: Tan G, Jensen MP, Thornby JI, Shanti BF. Validation of the Brief Pain Inventory for chronic nonmalignant pain. <i>J Pain</i>. 2004;5:133-137.]</p>	<b>Narrator:</b> While the BPI was first used in patients with cancer, it has since been validated in those with chronic nonmalignant pain. It is available in both short- and long-form versions.
103	BPI form is shown onscreen, with a close-up of the diagram on Question 2. When the first sentence is read, there will be an animation of an X being drawn on top of the lower back in the right-hand drawing.	<b>Narrator:</b> On the short form, patients are first asked to locate their pain on a drawing of a person.
104	<p>Close-up of Questions 3-6. Animation as follows:</p> <p>3. Circle the 7. 4. Circle the 3. 5. Circle the 6. 6. Circle the 6.</p>	<b>Narrator:</b> Then, they rate their pain on a scale of 0 to 10, with 0 being "No pain" and 10 being "Pain as bad as you can imagine."
105	<p>Medium shot of Question 9, A-D (page 2 of the form). Animation as follows:</p> <p>A. Circle the 5. B. Circle the 5. C. Circle the 3.</p>	<b>Narrator:</b> In the section where patients are asked how their pain affects their activities, a 0-10 scale is also used, with 0 being "Does not interfere" and 10 being "Completely interferes."

	D. Circle the 6.	
106	KTL onscreen.	<b>Narrator:</b> The long form has additional questions about patient demographics and medication use.